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January 23, 2025

VIA ECF

Honorable Cathy L. Waldor, U.S.M.J.
United States District Court
District of New Jersey
Martin Luther King Building & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: *In re Selenious Acid Litigation*, C.A. No. 24-cv-7791 (BRM)(CLW) (consolidated)

Dear Judge Waldor:

Pursuant to Paragraph 7 of the Court's Civil Case Management Order and the Court's January 6, 2025 Order (ECF No. 59), Plaintiff American Regent, Inc. ("ARI") and Defendants in the above-captioned matters submit this joint letter. Despite their best efforts, ARI and Defendants have not been able to reach resolution, so we jointly seek the Court's guidance to resolve the parties' dispute regarding a preliminary injunction briefing schedule.

I. Efforts to Resolve the Dispute

The Court's January 6, 2025 Order (ECF No. 59) directed the parties to meet and confer regarding a briefing schedule for ARI's upcoming motion for a preliminary injunction. The Court further ordered that the parties submit a briefing schedule where all briefing is completed on or before February 24, 2025. The parties exchanged initial proposed schedules and met and conferred on January 14, 2024, and have exchanged further correspondences. However, the parties have been unable to resolve all disputes. The parties' current competing proposals are set forth below and, for the Court's convenience, a comparison of the proposals is attached to this letter as Exhibit A.

A. Plaintiff ARI's Proposed Schedule

Event	ARI's Proposed Schedule
Plaintiff to submit Opening Brief, including and all supporting declarations and documents	Friday, January 17, 2025 ¹ (Page Limit: 40 pages at Times New Roman 12 pt font)

¹ To date, the parties have been unable to agree on a Confidentiality Order in this case. Consequently, for its opening brief which utilized the Confidential Information of each defendant group, the parties agreed that ARI would file its brief and any confidential exhibits under seal and serve Defendants' counsel unredacted copies of the filings on an Attorneys' Eyes Only basis under L. Pat. R. 2.2 until a confidentiality order is entered in this matter.

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	[Filed at ECF No. 85]
Defendants to submit Opposition Brief, including and all supporting declarations and documents	February 7, 2025 Total Page Limits: 40 pages at Times New Roman 12 pt font, to the extent defendants submit only a joint brief. *ARI opposes Defendants' proposal to submit individual briefs. However, to the extent the Court is willing to entertain Defendants' proposal, ARI requests that it be allowed to submit a 5-page Reply brief to each defendant group.
Plaintiff to submit Reply Brief and any reply declarations.	February 24, 2025 (Total Page Limit: 20 pages at Times New Roman 12 pt font, to the extent defendants submit only a joint brief) *ARI opposes Defendants' proposal to submit individual briefs. However, to the extent the Court is willing to entertain Defendants' proposal, ARI requests that it be allowed to submit a 5-page Reply brief to each defendant group.

B. Defendants' Proposed Schedule

Event	Defendants' Proposed Schedule
Plaintiff to submit Opening Brief	Friday, January 17, 2025 (Page Limit: 40 pages at Times New Roman 12 pt font)
Plaintiff to substantively respond to Defendants' interrogatories nos. 2-5, 8-9 and produce documents in response to Defendants'	January 27, 2025

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requests for production nos. 1-5, 7-8, 10, 12, 18-19 propounded on January 10.	
Defendants to submit Opposition Brief	<p><i>If Defendants are given a sur-reply:</i> February 7, 2025</p> <p><i>If Defendants are not given a sur-reply:</i> February 14, 2025</p> <p>(Total Page Limits: 40 pages at Times New Roman 12 pt font, to the extent defendants submit only a joint brief; otherwise 30 pages for a joint brief and 10 pages for each defendant family limited to issues of balance of hardships and/or infringement individual to said defendant)</p>
Defendants offer depositions of declarant(s), if applicable	<p><i>If Defendants are given a sur-reply:</i> February 10-11, 2025</p> <p><i>If Defendants are not given a sur-reply:</i> February 18-19</p>
Plaintiff to submit Reply Brief	<p><i>If Defendants are given a sur-reply:</i> February 14, 2025</p> <p><i>If Defendants are not given a sur-reply:</i> February 24, 2025</p> <p>(Total Page Limit: 20 pages at Times New Roman 12 pt font, to the extent defendants submit only a joint brief; otherwise 15 pages for a joint brief and 5 pages for each defendant family that filed an individual opposition brief)</p>
Plaintiff offers depositions of declarant(s), if applicable	<p><i>If Defendants are given a sur-reply:</i> February 17-19, 2025</p> <p><i>If Defendants are not given a sur-reply:</i> February 3-5</p>
Defendants to submit Sur-Reply Brief	February 24, 2025 (Total Page Limit: 15 pages at Times New Roman 12 pt font, to the extent defendants submit only a joint brief; otherwise

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	10 pages for a joint brief and 5 pages for each defendant family that files an individual opposition brief. All Sur-replies will be limited to invalidity/issues on which Defendants have the burden of proof.)
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II. Plaintiff ARI's Position

The Defendants' proposed schedule is overly complicated and includes various requirements that are not typical of preliminary injunction motions.

First, with respect to the issue of a bond, Plaintiff stated in its opening preliminary injunction brief that it believes that Defendants are not entitled to a bond. *See* Opening Brief (ECF No. 95) at 40. Plaintiff should not have been required to further address the issue of a bond in its opening brief. Defendants' bear the burden of demonstrating a bond is warranted. *LEGO A/S v. ZURU Inc.*, 799 F. App'x 823, 837–38 (Fed. Cir. 2020). The only case Defendants cite to support their position is a nearly 50-year old, non-patent case that explicitly did not decide “whether a court may dispense with the posting of a bond in a case where the injunction raises no risk of monetary harm to the defendant.” *Systems Operations, Inc. v. Scientific Games Dev. Corp.*, 555 F.2d 1131, 1146 (3d Cir. 1977). More recently, courts have found that “[r]ule 65(c) gives the district court wide discretion to set the amount of a bond, and even to dispense with the bond requirement where there has been no proof of likelihood of harm to those enjoined.” *LEGO*, 799 F.App'x at 837 (quoting *Corning Inc. v. PicVue Elecs., Ltd.*, 365 F.3d 156, 158 (2d Cir. 2004)).

Defendants have cited no authority contradicting the Federal Circuit's recent, clear statement in *LEGO* that Defendants' bear the burden of establishing entitlement to a bond. *Id.* at 837-38. Thus, should Defendants believe they are entitled to any bond, they should be required to make the initial showing in their responsive brief, and Plaintiff can reply, and the Court can decide on the issue of a bond².

Second, Defendants are not entitled to a sur-reply brief. Defendants seek a sur-reply brief, to which they are not entitled. ARI is moving for a preliminary injunction and, therefore, bears the burden to show it is entitled to relief. Therefore, ARI is entitled to the last word. *See, e.g., Paragon Component Sys. LLC v. Qualtim, Inc.*, C.A. No. 24-cv-00246, ECF No. 48 (E.D. Tenn. Nov. 25, 2024) (noting that sur-replies are “highly disfavored,” because they are usually “a strategic effort by the nonmoving party to have the last word on a matter”); *Vanocur Refractories*

² In a footnote, Defendants agree that, should they be granted a sur-reply, ARI should be allowed to address bond in its reply. *See supra*, n.4. However, this does not entitle Defendants to a sur-reply as Defendants are capable of including the entirety of their bond argument in their opposition papers.

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LLC v. Fosbel, Inc., C.A. No. 23-cv-2162, ECF No. 56 (N.D. Oh. Oct. 24, 2024) (same); *Lismont v. Alexander Binzel Corp.*, C.A. No. 12-cv-00592, ECF No. 47 at 6 (E.D. Va. Jun. 6, 2013) (same). This is further supported by Local Rule 7.1(d)(6), which provides that “[n]o sur-replies are permitted without permission of the Judge to whom the case is assigned.” A sur-reply brief may only be permitted by the Court to respond to new arguments raised in the reply brief, “or explain a position in the initial brief that the respondent refuted.” *Smithkline Beecham PLC v. Teva Pharm. U.S., Inc.*, Civ. A. Nos. 04-0215, 55, 2007 WL 1827208 at *1 (D.N.J. June 22, 2007) (citing cases); see also *Delrio-Mocci v. Connolly Props.*, Civ. A. No. 08-2753, 2009 WL 2989537 (D.N.J. Sep. 16, 2009) (finding a sur-reply was unnecessary because the defendant's reply brief did not raise any new arguments nor contain any statements requiring correction or further explanation).

Defendants argue that they should be entitled to a sur-reply because they have the burden of invalidity in the preliminary injunction phase. If Defendants’ approach is adopted, that would mean that any defendant in any patent infringement injunction motion would get a sur-reply. That is not the normal course. Further, Defendants misunderstand the applicable standards. “A patent holder seeking a preliminary injunction bears the burden of establishing a likelihood of success with respect to the patent’s validity.” *Entegris, Inc. v. Pall Corp.*, 490 F.3d 1340, 1351 (Fed. Cir. 2007); see also *Low Temp Indus., Inc. v. Duke Mfg. Co.*, No. 2021-2137, 2021 WL 6124455, at *3 (Fed. Cir. Dec. 28, 2021) (“In seeking a preliminary injunction, the patentee has the burden to show a likelihood of success regarding the patent’s validity; if the accused infringer raises ‘a substantial question regarding validity,’ the district court should find that the patentee has not shown a likelihood of success on the merits”). Further, Plaintiff has agreed to address objective indicia of non-obviousness in its opening brief so there will be no new arguments in Plaintiffs’ reply. Tellingly, Defendants fail to cite a single case allowing for a sur-reply in the context of a preliminary injunction. For example, the *Alston* and *Auto. Fin.* cases cited by Defendants dealt with summary judgment in a civil rights action and a motion to extend stay of execution of judgment in a tort case, respectively. See *Alston v. v. Forsyth*, 379 F. App’x 126, 129 (3d Cir. 2010); *Auto. Fin. Corp. v. DZ Motors, LLC*, C.A. No. 16-7955, 2021 WL 4922714, at *6 (D.N.J. Oct. 21, 2021).

Finally, while Defendants claim that the sur-reply will be limited to “issues of invalidity,” which is a joint community defense shared by all Defendants, they each are asking for “individual” briefs of five pages for each. The Court should deny the request for a sur-reply and order that the parties follow the usual course of briefing for injunction motions.

Third, broad expedited discovery is not warranted. Defendants now seek expedited discovery from ARI, that skirts the Federal Rules of Civil Procedure, despite telling this Court that “an expedited schedule is not justified” in this case (ECF No. 28 at 6) and having had ample opportunity to propound discovery. Defendants have been on notice of ARI’s impending preliminary injunction since at least August 29, 2024, when ARI circulated its first proposed schedule. See ECF No. 28 at 1. ***All the discovery for purposes of the preliminary injunction motion was served with ARI’s opening brief.*** Defendants cannot hold up injunction briefing by seeking full-blown discovery at this stage, which only serves to further Defendants’ prior actions

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to delay obtaining guidance from this Court on an orderly briefing schedule. Additionally, Defendants' schedule includes deadlines for depositions of deponents, yet Defendants have not articulated a reason why such depositions are necessary. Should Defendants identify a specific need for depositions after reviewing ARI's opening papers, the parties can address the issue at that time, and determine witness and counsel availability.

Fourth, Defendants should not be permitted individual briefs. All in, Defendants' proposal allows Defendants to submit nearly 150 total pages of briefing for its opposition. The issues in this case, regarding infringement and validity, as to each Defendant group is substantially overlapping. ARI address both issues in a single opening brief, and respectfully submits, that Defendants can do the same.

III. Defendants' Position

A. Defendants should be allowed a sur-reply

Because Plaintiff's Opening Brief for its Motion for Preliminary Injunction has not fully addressed issues for which Defendants bear the burden of proof (*i.e.*, patent invalidity), Defendants respectfully request the right to file a focused sur-reply addressing arguments raised for the first time in Plaintiff's Reply. Granting Defendants the right to file a sur-reply is necessary to ensure fairness, protect due process, and enable the Court to evaluate Plaintiff's motion on a complete record. Indeed, absent a sur-reply, the Court may need to independently evaluate un rebutted arguments or evidence in Plaintiff's Reply, thereby substantially prejudicing Defendants and undermining the very integrity of the decision-making process.

Given the posture of this case, where Plaintiff's Opening Brief precedes all discovery, Plaintiff could not and did not adequately address invalidity in its Opening Brief, and certainly not in any meaningful way (other than secondary considerations, for which Plaintiff bears the burden). On the contrary, while Plaintiff purported to preview some invalidity arguments Defendants *might* make—pointing to Defendants' notice letters and the prosecution history of Plaintiff's patents—Plaintiff reserved its right to respond to invalidity arguments that Defendants make in opposing Plaintiff's PI, including by introducing new arguments. Defendants will effectively raise invalidity for the first time in their Opposition. While Plaintiff has the burden of demonstrating likelihood of success, Defendants bear the burden of raising invalidity defenses. *See, e.g., Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1377 (Fed. Cir. 2009) ("If, instead, the alleged infringer responds to the preliminary injunction motion by launching an attack on the validity of the patent, the burden is on the challenger to come forward with evidence of invalidity . . ."). Terminating the parties briefing at the reply stage robs Defendants of the opportunity to address new arguments, *e.g.*, against invalidity, raised for the first time by Plaintiff in its Reply. Denying such an opportunity unfairly prejudices Defendants and improperly shields Plaintiff's arguments from proper scrutiny.

While sur-replies are not routinely permitted under N.J. Local Rule 7.1(d)(6), this court has discretion to allow them in the interest of justice, particularly when new arguments or evidence

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are raised in a reply brief. *See, e.g., Ex. B., Otsuka Pharmaceutical Co., Ltd v. Torrent Pharmaceuticals Limited, Inc. et al.*, No. 1:14-cv-01078-JBS-KMW (D. N.J.) (Dkt. No. 79) at 10 (permitting sur-replies as a part of preliminary injunction briefing schedule). Fairness requires Defendants should have the opportunity to respond to new arguments raised for the first time in a reply. *See, e.g., Alston v. Forsyth*, 379 F. App'x 126, 129 (3d Cir. 2010) ("There is cause for concern where a movant presents new arguments or evidence for the first time in a summary judgment reply brief, particularly if the District Court intends to rely upon that new information in granting summary judgment to the movant."). Courts have routinely held that reply briefs cannot be used to introduce new arguments or evidence, particularly when the opposing party has no right to respond. *See, e.g., Auto. Fin. Corp. v. DZ Motors, LLC*, No. CV167955MASDEA, 2021 WL 4922714, at *6 (D.N.J. Oct. 21, 2021) ("But courts in this District routinely refuse to consider arguments raised for the first time on reply because adversaries have no opportunity to respond to newly minted arguments contained in reply briefs.") (internal citations and quotations omitted).

Yet, that is exactly the case here. There is currently no record developed on invalidity in this case, and Plaintiff could not, therefore, address *Defendants'* invalidity positions substantively in its Opening Brief. Moreover, the Court may decide Plaintiff's Motion on the papers. In addition to the substantial prejudice to Defendants from being unable to respond to Plaintiff's invalidity arguments, the absence of a sur-reply could cause the Court to rely on unchallenged arguments or evidence raised for the first time in Plaintiff's Reply.

Given the foregoing, Defendants respectfully request that the Court permit a sur-reply. This step is necessary to protect Defendant's due process rights, prevent unfair prejudice, and ensure the Court's consideration of all relevant arguments.

B. Expedited discovery is warranted for the preliminary injunction briefing

Defendants, frankly, are surprised that Plaintiff refuses to agree to expedited discovery and a schedule including depositions of its and Defendants' declarants. Plaintiff has chosen to bring its preliminary injunction motion shortly after adding a second patent to the suit and only three weeks after the parties were finally able to agree on a schedule for contentions and other discovery in the case. Regardless of the content of Plaintiff's motion and supporting declarations, it is customary in preliminary injunction cases for expedited discovery and depositions of any declarants to be set as part of the schedule, especially those in the Hatch-Waxman context. *See Ex. C, Bausch & Lomb, Inc. v. Slayback Pharma LLC*, No. 3:21-cv-16766 (RK) (RLS) (D. N.J.) (Dkt. Nos. 299 (159 redacted) and 162 (requiring depositions of parties' declarants in preliminary injunction proceedings as part of schedule)); *see also Ex. D, Astellas Pharma Inc. v. Lupin Ltd.*, No. 23-cv-819-JFB-CJB (D. Del.) (Dkt. No. 92) (setting preliminary injunction schedule in Hatch-Waxman Act providing for depositions of declarants). Further, the Court should simply not permit Plaintiffs to withhold critical documents pertaining to their alleged inventions and potential statutory bars, which could themselves invalidate the asserted patents. Any suggestion otherwise from Plaintiff should be disregarded. Defendants' proposed schedule includes these usual and necessary deadlines, which should be part of any preliminary injunction schedule entered by the Court.

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C. Plaintiff should address the bond issue first

Plaintiff, who is seeking to enjoin Defendants from entering the market, should be required to be the first to address substantively³ the issue of a bond. Fed. R. Civ. P. 65(c) (“The court may issue a preliminary injunction or a temporary restraining order only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained.”); *see also Systems Operations, Inc. v. Scientific Games Dev. Corp.*, 555 F.2d 1131, 1145 (3d Cir. 1977) (“We hold that in these circumstances a district court commits reversible error when it fails to require the posting of a security bond by the successful applicant for a preliminary injunction.”). Citing Second Circuit law (and the *Lego* case applying Second Circuit law), Plaintiff wrongly suggests the requirement for a bond has been significantly relaxed. It has not. *See, e.g., Boynes v. Limetree Bay Ventures LLC*, 110 F.4th 604, 611 (3d Cir. 2024) (“We have held that posting a bond is ‘almost mandatory’; any exceptions are ‘rare.’”) (quoting *Frank's GMC Truck Ctr., Inc. v. Gen. Motors Corp.*, 847 F.2d 100, 103 (3d Cir. 1988)). Especially since Plaintiff asserts that a bond is not required, Plaintiff should be required to explain why before Defendants address the issue in their Opposition.⁴

D. Each defendant should be allowed a reasonable number of pages to address issues particular to that defendant

Plaintiff moved for a preliminary injunction against a total of eleven defendant families, not all of which are identically situated. While the Defendants anticipate they will be able to respond to much of (and perhaps all) Plaintiff’s arguments jointly, Defendants have just received and are still reviewing Plaintiff’s Opening Brief. As such, Defendants seek to reserve the right to file individual oppositions and sur-replies for arguments that are individual to a given defendant, if necessary. Defendants likewise propose that Plaintiff be given a reasonable number of additional pages to respond to any individual defendant’s submission.

Plaintiffs oppose Defendants filing separate briefing on Defendant-specific issues, instead attempting to force Defendants to submit one combined brief, as Plaintiff did. Plaintiff’s proposal is not feasible. In particular, information regarding Defendants’ respective ANDAs and launch plans (*e.g.*, the information related to Plaintiff’s infringement arguments) is being shared between Defendants only on an Outside Attorneys’ Eyes Only basis, meaning if Defendants are forced to file consolidated briefs on infringement, no Defendant’s in-house attorneys would be able to review this portion of the consolidated briefing.

³ While Plaintiff asserted in its Opening Brief that Defendants are not entitled to a bond, it offered no supporting authority, evidence, or argument.

⁴ If Defendants are granted a Sur-Reply Brief, Defendants agree that Plaintiff can address bond in its Reply Brief, so Defendants can respond to any arguments from Plaintiff regarding bond in sur-reply.

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To the extent Defendants submit joint briefing on all issues, Defendants’ position would allow both parties a total of 55 pages of briefing. Plaintiff’s argument that Defendants’ position “allows Defendants to submit nearly 150 total pages of briefing” also grossly inflates Defendants’ total amount of briefing. It appears Plaintiff took the number of pages Defendants could utilize for individualized issues, such as non-infringement (*e.g.*, 10 pages/Defendant in Opposition)—which would necessarily be addressing the same issues, but individualized for each Defendants’ specific information—and multiplied it by 11 to inflate its allegation that Defendants get 150 total pages of briefing.

* * *

Should the Court require anything further, the parties will make themselves available at the Court’s convenience. The parties thank the Court for its time and assistance in this matter.

Respectfully submitted,

s/ Charles H. Chevalier

Charles H. Chevalier

cc: Counsel of Record (via ECF and e-mail)